

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of )  
Serge BRAUN ) Group Art Unit: Unassigned  
Application No.: Unassigned ) Examiner: Unassigned  
Filed: February 21, 2001 )  
For: TREATMENT OF IMMUNE )  
DISEASES )

**PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to examination, please amend the above-captioned application as follows:

**IN THE CLAIMS:**

Kindly cancel claim 1 without prejudice or disclaimer.

2. (Amended) The [use] method of claim [1] 12, wherein said immune disease is a demyelinating disease.

3. (Amended) The [use] method of claim [1 or 2, wherein said] 12, wherein said immune disease is an autoimmune disease.

4. (Amended) The [use] method of claim 3, wherein said autoimmune disease is multiple sclerosis.

5. (Amended) The [use] method of [anyone of claims 1 to 4] claim 12, wherein the nucleic acid is DNA.

6. (Amended) The [use] method of claim 5, wherein the DNA is naked DNA.

7. (Amended) The [use] method of claim 5, wherein the DNA is associated with a transfection-facilitating vehicle.

8. (Amended) The [use] method of claim 7, wherein said transfection-facilitating vehicle is selected from the group consisting of viral particles, cationic lipids, cationic polymers and polypeptides.

9. (Amended) The [use] method of [anyone of claims 1 to 8] claim 12, wherein said beta-interferon is human beta-interferon.

10. (Amended) The [use] method of [anyone of claims 1 to 9] claim 12, wherein said beta-interferon comprises a secretory signal sequence.

11. (Amended) The [use] method of [anyone of claims 11 to 14] claim 12, wherein said [pharmaceutical composition administration] nucleic acid is suitable for administration by injection.

Kindly add claims 12-23:

--12. A method for the treatment of an immune disease comprising administering an effective amount of a nucleic acid capable of expressing beta-interferon to a patient in need of such treatment.

13. A pharmaceutical composition for the treatment of an immune disease comprising an effective amount of a nucleic acid capable of expressing beta-interferon and a pharmaceutically acceptable carrier therefor.

14. The pharmaceutical composition of claim 13, wherein said immune disease is a demyelinating disease.

15. The pharmaceutical composition of claim 13, wherein said immune disease is an autoimmune disease.

16. The pharmaceutical composition of claim 15, wherein said autoimmune disease is multiple sclerosis.

17. The pharmaceutical composition of claim 13, wherein the nucleic acid is DNA.

18. The pharmaceutical composition of claim 17, wherein the DNA is naked DNA.
19. The pharmaceutical composition of claim 17, wherein the DNA is associated with a transfection-facilitating vehicle.
20. The pharmaceutical composition of claim 19, wherein said transfection-facilitating vehicle is selected from the group consisting of viral particles, cationic lipids, cationic polymers and polypeptides.
21. The pharmaceutical composition of claim 13, wherein said beta-interferon is human beta-interferon.
22. The pharmaceutical composition of claim 13, wherein said beta-interferon comprises a secretory signal sequence.
23. The pharmaceutical composition of claim 13, which is suitable for administration by injection.--

**REMARKS**

Entry of the foregoing amendment(s) is respectfully requested.

The claims have been amended to eliminate multiple dependency and to place them in better condition for U.S. patent practice.

Should the Examiner have any questions concerning the subject application, a telephone call to the undersigned would be appreciated.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 

\_\_\_\_\_  
Teresa Stanek Rea  
Registration No. 30,427

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620

Date: February 21, 2001